Stago

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## Attachment – 6

## 510(k) SUMMARY

K082248

DEC 12 2008

**Diagnostica Stago's STA Satellite®**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:**

Umberto V. Parrotta
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Phone: (973) -631-1200, x-2044
Facsimile: (973) -695-0095

Contact Person: Umberto V. Parrotta

Date Prepared: August 06, 2008

**Name of Modified Device and Name/Address of Sponsor:**

STA Satellite®

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

**Common or Usual Name:**

- IVD Coagulation Device/Instrument.
- Automated and Semi-Automated Hematology Device.
- Multi-Parametric Analyzer

**Classification Name:**

System, Multipurpose for In Vitro Coagulation Studies

**Predicate Devices:**

- Diagnostica Stago SAS' STA-R® Automated Multi-Parametric Analyzer (K983460).
- Sigma Diagnostic Inc.'s AMAX Destiny Coagulation Analyzer (K021162).

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# Attachment – 6

## 510(k) SUMMARY

**Predicate Device Manufacturer:**

Diagnostica Stago SAS

**Purpose of the Special 510(k) notice:**

The STA Satellite® is a modification to the company's own legally marketed device, STA-R®.

**Indication/Intended Use:**

The STA Satellite™ Automated Multi-Parametric AnalyzerSatellite® Automated Multi-Parametric Analyzer is a fully automatic clinical instrument indicated and intended for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

**Technological Characteristics:**

The STA Satellite® Automated Multi-Parametric Analyzer is designed as a fully automatic bench-top system. Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis, and reporting of results are performed automatically. A central processing unit controls instrument functions such as, management of patient results, quality control, system supervision, support for instrument maintenance, and work load optimization. The STA Satellite® is the bench-top version of the company's STA-R®, legally marketed predicate device.

The instrument utilizes Diagnostica Stago reagents in addition to open adaptation of other currently available reagents. Barcoding of test reagents, calibrators, and controls facilitate their use on the system and permits reagent management simple. Manual entry of reagent information enables the use of non-barcoded reagents.

The instrument performs multiple test methodologies in random access as selected by the user. These include clotting time or clot-based tests (i.e. Chronometricchronometric) measurements and photometric assays (at specific wave lengths) on plasma samples. The principle of the chronometric method consists in measuring the variation of the oscillation amplitude of the ball (in the cuvette). A decrease in oscillation amplitude corresponds to an increase in the viscosity of the media (*i.e.*., coagulation). The principle of the photometric measurements on the instrument is based on measured absorbance (also referred

to as Optical Density, or OD) of monochromatic light of predetermined wavelength passing through the cuvette as a (clotting) reaction takes place.

**Performance Data:**

Comparison of the device and predicate device performance characteristics was conducted during the performance validation study. Validation of the STA - Satellite® with the STA-R® predicate device was performed at an internal site and two external sites.

Test samples were analyzed in duplicate on the STA -Satellite and the STA-R. Results were analyzed by standard statistical methods (mean, standard deviation, 95% confidence intervals, correlation between instruments and comparison to acceptance criteria).

Correlation data between the STA -Satellite and the STA-R were within the acceptance criteria for all assays and all sites (see Table below for assays performed). There was no significant difference or clinically significant difference between the results from the instruments between the sites and instruments.

In addition, the STA Satellite® is CE Marked and has been in commerce in France since September 2004. There have been no adverse performance-related events or analogous complaints resulting in recalls with regards to its design during this time that would raise questions of safety and effectiveness.

In conclusion, performance validation study comparison results between the STA Satellite® and the STA-R device instrument and predicate device indicate statistically similar results. , Analysis of which demonstrates substantial equivalence.

**Substantial Equivalence:**

The STA Satellite® has the same intended use and similar indications, principles of operation, and technological characteristics as the STA-R® and the AMAX predicate devices. The differences in the external architecture, software, and chronometric viscosity detection do not raise any new questions of safety or effectiveness. Performance data and risk assessment demonstrate that the STA Satellite® is as safe and effective as STA-R®the predicate devices. Thus, the STA Satellite® is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diagnostica Stago, Inc.
C/o Umberto V. Parrotta
Five Century Drive
Parsippany, New Jersey 07054

DEC 12 2008

Re: k082248
Trade/Device Name: STA Satellite® Automated Multi-Parametric Analyzer
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: October 03, 2008
Received: October 06, 2008

Dear Mr. Parrotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Marian Chan, PhD
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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**Attachment – 2A**

## Indications for Use Form

510(k) Number (if known): K082248

Device Name:

Satellite™ Automated Multi-Parametric Analyzer

Indications for Use:

The Satellite™ is a fully automatic clinical instrument designed for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use ✓ 510(k)___ OR K082248 Over-The-Counter Use___
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)